

Amendments to the Claims

This listing of claims will replace all prior versions, and listings of claims in the application:

Claim 1 (currently amended): A pharmaceutical composition for the oral administration of an active agent having low water solubility, wherein

a) the active agent is dispersed in an aqueous formulation base, said aqueous formulation base further comprising polyvinyl alcohol; and

b) the solubilizing agent is suitable for the formation of an aqueous dispersion of nanoparticles;

which is characterized in that the solubilizing agent is a pharmaceutically acceptable polymer which is resistant to gastric juices and soluble in intestinal juices.

Claim 2 (original): A pharmaceutical composition according to claim 1, wherein the polymer, which is resistant to gastric juices and soluble in intestinal juices is a copolymer from monomers selected from the group consisting of methacrylic acid, methacrylic acid esters, acrylic acid and acrylic acid esters.

Claim 3 (previously presented): A pharmaceutical composition according to claim 1, wherein said pharmaceutically acceptable polymer, which is resistant to gastric juices and soluble in intestinal juices, is a pharmaceutically acceptable cellulose derivative selected from the group consisting of hydroxypropyl methyl cellulose acetate succinate (HPMCAS), hydroxypropyl methyl cellulose phthalate (HPMCP), cellulose acetate phthalate (CAP), and cellulose acetate trimellitate (CAT).

Claim 4 (previously presented): A pharmaceutical composition according to claim 2, wherein said pharmaceutically acceptable polymer is a 1:1-up to 1:2-copolymer from monomers selected from the group consisting of methacrylic acid and methacrylic acid lower alkyl esters.

Claim 5 (original): A pharmaceutical composition according to claim 4, wherein the copolymer is a 1:1-up to 1:2-copolymer of methacrylic acid and methacrylic acid methyl ester.

Claim 6 (original): A pharmaceutical composition according to claim 2, wherein the copolymer is a 1:1-copolymer of methacrylic acid and acrylic acid ethyl ester.

Claim 7 (cancelled).

Claim 8 (original): A pharmaceutical composition according to claim 1, wherein the formulation base contains water soluble additives suitable for incorporation in a dosage form intended for oral administration.

Claims 9 to 11 (cancelled).

Claims 12 to 26 (cancelled)

Claim 27 (currently amended): A process for preparing a pharmaceutical composition for oral administration of an active agent having low water solubility comprising the steps of:

- a) preparing an aqueous gel comprising a hydrophilic polymer;
- b) preparing a solution of an organic solvent comprising said active agent and a pharmaceutically acceptable polymer, wherein said pharmaceutically acceptable polymer is chosen from at least one of (i) a copolymer selected from the group consisting of (a) methacrylic acid or acrylic acid and (b) methyl or ethyl esters of acrylic or ethacrylic acid monomers, (ii) polyvinyl acetate phthalate (PVAP), (iii) hydroxypropyl methyl cellulose acetate succinate (HPMCAS), (iv) hydroxypropyl methyl cellulose phthalate (HPMCP), (v) cellulose acetate phthalate (CAP) and, (vi) cellulose acetate trimellitate (CAT), and said pharmaceutically acceptable polymer is resistant to gastric juices and soluble in intestinal juices;
- c) combining said gel from step a with said solution of step b; and
- d) adding pure water to said combination of step c to form a homogenous aqueous dispersion of nanoparticles.

Claim 28 (previously presented): The process according to claim 27, wherein said aqueous gel further comprises a water soluble salt.

Claim 29 (previously presented): The process according to claim 27, wherein said hydrophilic polymer is polyvinyl alcohol.

Claim 30 (previously presented): The process according to claim 27, further comprising the step of lyophilizing said homogenous aqueous dispersion of nanoparticles to a lyophilizate.

Claim 31 (previously presented): A pharmaceutical composition obtained by said process of claim 27.

Claim 32 (new): A pharmaceutical composition according to claim 1, wherein said active agent is selected from the group consisting of immuno-suppressive agents, non-steroidal anti-inflammatory agents, calcium channel blockers., immunomodulators, and antibiotic agents.

Claim 33 (new): A pharmaceutical composition according to Claim 1, wherein the polyvinyl alcohol has a degree of hydrolysis greater than 70%.